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Display Date	8-6-99
Publication Date	8-9-99
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-0185]

**Agency Information Collection Activities: Proposed Collection; Comment Request;  
Cosmetic Product Voluntary Reporting Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Cosmetic Product Voluntary Reporting Program.

**DATES:** Submit written comments on the collection of information by *(insert date 60 days after date of publication in the Federal Register)*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Cosmetic Product Voluntary Reporting Program—21 CFR 720.4, 720.6, and 720.8(b) (OMB Control Number 0910–0030—Extension)**

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests under part 720 (21 CFR part 720), but does not require, that firms that manufacture, pack, or distribute cosmetics file with the agency an ingredient statement for each of their products (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 2512 entitled “Cosmetic Product Ingredient Statement,” and Form FDA 2512a, a continuation form. Changes in product formulation (§ 720.6)

are also reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514 entitled “Discontinuance of Commercial Distribution of Cosmetic Product Formulation” (§ 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA uses the information received on these forms as input for a computer-based information storage and retrieval system. These voluntary formula filings provide FDA with the best information available about cosmetic product formulations, ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. FDA’s data base also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise harmful to the general public health. The information provided under the Cosmetic Product Voluntary Reporting Program assists FDA scientists in evaluating reports of alleged injuries and adverse reactions to the use of cosmetics. The information also is utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch-test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on frequency of use.

The Cosmetic Product Voluntary Reporting Program was suspended during fiscal year (FY) 1998 because of a lack of funding and was reinstated at the beginning of FY 1999. Participation

returned to the previous level. Thus, FDA estimates that the burden of this collection of information will remain the same as the estimate presently on file with OMB.

FDA estimates the burden of this collection of information as follows:


TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.4 (New submissions)	FDA 2512/FDA 2512a	550	4.2	2,310	0.5	1,155
720.6 (Amendments)	FDA 2512/2512a	550	1.4	770	0.33	254
720.6 (Notices of discontinuance)	FDA 2514	550	4.5	2,500	0.1	250
720.8 (Requests for confidentiality)		2	1.0	2	1.5	3
Total						1,662

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: August 2, 1999



William K. Hubbard  
Senior Associate Commissioner for Policy, Planning and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

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